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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,076	10/03/2001	John A.T. Young	960296.97745	9060

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EXAMINER

MINNIFIELD, NITA M

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,076

Applicant(s)

YOUNG ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13, 19-21 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13, 19-21 and 27-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 2 sheets
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicants' amendment filed January 10, 2005 is acknowledged and has been entered. Claims 1-10, 14-18 and 22-26 have been canceled. Claims 11-13 and 19 have been amended. New claims 27-31 have been added. Claims 11-13, 19-21 and 27-31 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment and/or comments with the exception of those rejections discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 11-13, 19-21 and 27-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "an amino acid sequence". It is not clear if Applicants intend a portion of the sequence, as in a fragment, or the entire sequence. Claims 27, 28, 30 and 31 specifically recite "an amino acid sequence" as well as a Markush group that comprises SEQ ID NO:2, amino acids 27-321 of SEQ ID NO: 2 and amino acids 28-320 of SEQ ID NO:2 (see claim 27 for example). Does Applicant intend an amino acid sequence of SEQ ID NO:2 to be the entire sequence set forth in SEQ ID NO: 2 or a fragment of SEQ ID NO:2? Does Applicant intend an amino acid sequence of amino acids 27-321 of SEQ ID NO:2 to be the amino acids 27-321 of SEQ ID NO:2 or some

fragment or portion of amino acids 27-321 of SEQ ID NO:2? Clarification is requested.

4. Claims 11-13, 19-21 and 27-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al 6569662.

Tang et al discloses the polynucleotide sequence that encodes the polypeptide that comprises a fragment of SEQ ID NO: 2, 6 8 and 10, see SEQ ID NO: 8 of Tang et al 6569662. Tang et al also discloses methods of producing a protein, vectors and host cells (see cols. 2-3; cols. 9-19).

The prior art anticipates the claimed invention. The prior art anticipates the claimed invention by disclosing the polynucleotide having the same or similar characteristics as claimed. The polynucleotide in the prior art is believed to inherently possess properties which anticipates the claimed invention or if they are not the same the polynucleotide, would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the polynucleotide of the prior art is evidenced to meet the limitations of the claimed polynucleotide, in the absence of evidence to the contrary.

Since the Office does not have the facilities for examining and comparing applicants' polynucleotide with the polynucleotide of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed product and the product of the prior art (i.e., that the polynucleotide of the prior art does not possess the same material structural and functional characteristics of the claimed polynucleotide) See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection is maintained for the reasons of record. Applicant's arguments filed January 10, 2005 have been fully considered but they are not persuasive. Applicants have asserted that SEQ ID NO:8 of Tang et al. encodes a polypeptide of 297 amino acids (the Tang polypeptide). The Tang polypeptide differs from SEQ ID NO:2 of the present invention (an anthrax toxin receptor of 368 amino acids long) in a carboxyl end portion from amino acid 268. Applicants have asserted that new claims 27-29 are directed at a polynucleotide that comprises a nucleotide sequence that encodes the full length SEQ ID NO:2 (368 amino acids), amino acids 27-321 of SEQ ID NO:2, or amino acids 28-320 of SEQ ID NO:2. Since each of the above amino acid sequences recited in claims 27-29 contains a segment (amino acid 268 to the C-terminus) that is neither disclosed nor rendered obvious by Tang et al., claims 27-29 are novel and unobvious over Tang et al.

However, it is noted that the claims still recite "the polynucleotide comprising a nucleotide sequence encoding *an amino acid sequence...* of SEQ ID NO:2, amino acids 27-321 of SEQ ID NO:2...". It would appear that the sequences disclosed in Tang et al are the same as those claimed by Applicants. Tang et al discloses amino acids 1-268 of Applicants' SEQ ID NO:2 and therefore would disclose *an amino acid sequence...* of SEQ ID NO:2, amino acids 27-321 of SEQ ID NO:2, amino acids 28-320 of SEQ ID NO:2.

Applicants have asserted that new claims 30 and 31 are directed at a polynucleotide that consists of a nucleotide sequence that encodes amino acids 41-227 of SEQ ID NO:2, amino acids 42-222 of SEQ ID NO:2, or amino acids 44-216 of SEQ ID NO:2. Although Tang et al. disclose a full-length polypeptide (coded by SEQ ID NO:8) that contains the above fragments recited in claims 30 and 31, the recited fragments *per se* are not specifically disclosed by Tang et al. Neither

was there any explicit or implicit suggestion in Tang et al. that these particular fragments are useful and should be made. Therefore, claims 30 and 31 are novel and unobvious over Tang et al.

However, it is noted that the claims still recite “the polynucleotide comprising a nucleotide sequence encoding *an amino acid sequence...* of SEQ ID NO:2, amino acids 27-321 of SEQ ID NO:2...”. It would appear that the sequences disclosed in Tang et al are the same as those claimed by Applicants. Tang et al discloses amino acids 1-268 of Applicants’ SEQ ID NO:2 and therefore would disclose *an amino acid sequence...* of SEQ ID NO:2, amino acids 27-321 of SEQ ID NO:2, amino acids 28-320 of SEQ ID NO:2.

5. Claims 11-13, 19-21 and 27-31 are rejected under 35 U.S.C. 102(a) as being anticipated by WO200134626-A1 (Accession #:AAD5303), Accession # BC012074 from NCBI.

It should be noted that this rejection was previously set forth and withdrawn. However, this rejection has been re-applied in view of Applicants’ amendment to the claims.

The prior art discloses a polynucleotide sequence that has 99.7% similarity/identity with the claimed SEQ ID NO: 1. The prior art discloses the claimed polynucleotide sequence of SEQ ID NO: 1 or a fragment thereof. The prior art discloses methods for producing the polypeptide encoded by the polynucleotide sequence.

The claimed invention is anticipated by the prior art. It is noted that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore,

if the prior art discloses the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The prior art anticipates the claimed invention by disclosing the polynucleotide having the same or similar characteristics as claimed. The polynucleotide in the prior art is believed to inherently possess properties which anticipates the claimed invention or if they are not the same the polynucleotide, would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the polynucleotide of the prior art is evidenced to meet the limitations of the claimed polynucleotide, in the absence of evidence to the contrary.

Since the Office does not have the facilities for examining and comparing applicants' polynucleotide with the polynucleotide of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed product and the product of the prior art (i.e., that the polynucleotide of the prior art does not possess the same material structural and functional characteristics of the claimed polynucleotide) See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. Claims 27-31 are rejected under 35 U.S.C. 102(a) or (b) as being anticipated by St. Croix et al (2000).

It should be noted that this rejection was previously set forth and withdrawn. However, this rejection has been re-applied in view of Applicants' amendment to the claims.

The prior art discloses the polynucleotide sequence as set forth in claimed SEQ ID NO: 1 or a fragment thereof (see accession # AF279145).

The claimed invention is anticipated by the prior art. It is noted that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art discloses the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01 .

The prior art anticipates the claimed invention by disclosing the polynucleotide having the same or similar characteristics as claimed. The polynucleotide in the prior art is believed to inherently possess properties which anticipates the claimed invention or if they are not the same the polynucleotide, would none the less render the claims obvious because it possesses similar characteristics and functions in the same manner as claimed in the instant application. Thus, the polynucleotide of the prior art is evidenced to meet the limitations of the claimed polynucleotide, in the absence of evidence to the contrary.

Since the Office does not have the facilities for examining and comparing applicants' polynucleotide with the polynucleotide of the prior art, the burden is on applicant to show a novel or unobvious differences between the claimed product and the product of the prior art (i.e., that the polynucleotide of the prior art does not possess the same material structural and functional characteristics of the claimed polynucleotide) See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. No claims are allowed.
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The

fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script, appearing to read 'N. M. Minnifield', is written over a printed name.

Primary Examiner

Art Unit 1645

NMM

March 31, 2005